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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,219	03/11/2004	Matilde Bustos De Abajo	U 015070-8	3487

140 7590 07/31/2006

LADAS & PARRY  
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NEW YORK, NY 10023

EXAMINER
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WEHBE, ANNE MARIE SABRINA

ART UNIT	PAPER NUMBER
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1633

DATE MAILED: 07/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/798,219

**Applicant(s)**

ABAJO ET AL.

**Examiner**

Anne Marie S. Wehbe

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-11 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

### **DETAILED ACTION**

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-10, drawn to “use” of a polynucleotide sequence encoding cardiotrophin-1 (CT-1) in the manufacture of a composition, classified in class 435, subclass 320.1.
- II. Claims 1-8, drawn to “use” of a cardiotrophin-1 polypeptide in the manufacture of a composition, classified in class 530, subclass 350.
- III. Claim 11, drawn to a method of cultivating hepatocytes comprising adding a viral vector bearing a polynucleotide sequence that expresses and codes for CT-1 to a medium, classified in class 435, subclass 455.
- IV. Claim 11, drawn to a method of cultivating hepatocytes comprising adding CT-1 polypeptide to a medium, classified in class 435, subclass 405.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as products which share an alleged common utility of manufacturing a composition with various intended uses in the treatment of hepatic conditions but the common utility is not linked to a substantial structural feature. The products in this relationship are distinct if either or both of the following can be shown: (1) that the products encompass embodiments that are not required to perform the common utility or (2) that the products as claimed can be used to perform another utility. In this case, a cardiotrophin-1 (CT-1) polypeptide is chemically, structurally, and functionally distinct from a polynucleotide encoding

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CT-1. Further, polypeptides and nucleic acids have substantially different modes of activity.

Thus, the products do not share a substantial structural feature. Further, the CT-1 polynucleotides can be used to produce the CT-1 protein in tissue culture, or can be used in in vitro nucleic acid binding assays or PCR. Thus, for the reasons set forth above, the search for each invention is not co-extensive and it would place an undue burden on the examiner to search and examine both inventions together.

Inventions III and IV Inventions are directed to related methods. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the methods of cultivating hepatocytes with a viral vector encoding CT-1 do not overlap in scope with methods of cultivating hepatocytes with a CT-1 polypeptide as the cardiotrophin-1 (CT-1) polypeptide is chemically, structurally, and functionally distinct from a polynucleotide encoding CT-1. Further, CT-1 polypeptide and nucleic acid encoding CT-1 have substantially different modes of operation and function.

Therefore, for the reasons set forth above, the search for each invention is not co-extensive and it would place an undue burden on the examiner to search and examine both inventions together.

The “uses” of inventions I and II to manufacture a composition are further distinct from the methods of inventions III and IV as the products and compositions of inventions I and II can be used in numerous methods not related to the methods of culturing hepatocytes of inventions III and IV. As such, the search for each invention is not co-extensive and it would place an undue burden on the examiner to search and examine all inventions together.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, different classification, and different search requirements, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. If the examiner is not available, the examiner's supervisor, Dave Nguyen, can be reached at (571) 272-0731. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197. Representatives are available daily from 6am to midnight (EST). When calling please have your application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D  
PRIMARY EXAMINER

